Cabinet for Health and Family Services
Office of the Inspector General

Overview and Demonstration of Enhanced KASPER (eKASPER) Program
March 16, 2005

Kentucky
UNBRIDLED SPIRIT

CONTENTS

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Governor

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Secretary

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Welcome –

Thank you for taking the time out of your busy schedule to be with us today. The Cabinet for Health and Family Services is proud to take this opportunity to introduce the enhanced Kentucky All Schedule Prescription Electronic Reporting (KASPER) system. In 1999, Kentucky became the first state to require pharmacies to report data on all scheduled II-V drugs dispensed, and to generate reports to prescribers, law enforcement, and other authorized requestors, to enhance patient care and to inhibit the flow of legal drugs into the illegal market. Today, over twenty states have prescription monitoring programs (PMPs), and many more are being planned.

Although KASPER had an immediate impact on the ability to monitor and control drug diversion, the original manual system of paper requests and faxed responses, and the unanticipated demand on the system, made it difficult to provide data to requestors in a timely fashion. Although the Cabinet has now improved the "paper and fax" system to less than a business day turnaround, no small feat considering existing resources, our practitioner and law enforcement requestors have made it clear that "real time" access to the data is the number one priority in improving an already excellent system. In 2003, the Legislature responded with a $1.4 million appropriation for the Cabinet to make web-based real time access to KASPER data a reality. The Cabinet is pleased to announce that we have done just that. Today you will see that Kentucky is still leading the nation.

Enhanced KASPER provides web-based, real time access to reports, while still responding to paper requests under the original system. As an example, an emergency room physician will be able to log onto the web system using a secure password and request information on a patient. Within minutes a notice will appear in the physician's inbox that the report is available for review. This can be done while the patient is present with the physician, increasing the ability of the physician to provide better care and prevent abuse. The physician's ability to provide quality health care is significantly improved. Also, a pharmacist who is presented with a questionable prescription can access a report while the customer is in the store. That pharmacist's ability to provide quality services and prevent abuse is significantly enhanced. We understand that our physicians, pharmacists, and all practitioners with access to the system are on the front lines in our fight against drug diversion. Finally, a law enforcement or regulatory board professional investigating a diversion case will be more efficient in the identification of drug abuse, bringing some resource relief to an area where resources are so desperately needed, at the same time making Kentucky a safer environment for all our citizens.

Again, thank you for your time and your continued cooperation and support in Kentucky's fight against prescription drug diversion and abuse.

Sincerely,

James W. Holsinger, Jr., M.D.
Secretary

Robert J. Benvenuti, III, Esq.
Inspector General

K*entucky* **A***ll* **S***chedule* **P***rescription* **E***lectronic* **R***eporting*

Timeline

2005
- ü eKASPER implementation
- ü 2004 Hal Rogers Grant will be completed June 30, 2005 and report submitted to DOJ
- ü 2005 Hal Rogers Grant application submitted
  - ∉ Isolate KASPER technical issues
  - ∉ Develop a means to monitor KASPER system access by users to authenticate user IDs
  - ∉ Develop trend reports from KASPER data.
  - ∉ Streamline KASPER staff business processes to maximize effectiveness.

2004
- ü Governor Fletcher signs SB14 into law
- ü Drug Enforcement and Professional Practices Branch moved from the Department for Public Health to the Office of the Inspector General, Division of Fraud, Waste and Abuse/Identification and Prevention.
- ü OIG assumes responsibility for the continued development of eKASPER and administration of the 2004 Hal Rogers Grant.
- ü 2004 Hal Rogers Grant
  - ∉ Survey KASPER system users
  - ∉ Form focus/work groups to study KASPER
  - ∉ Contract with Kentucky Injury Prevention and Research Center to determine effectiveness of KASPER in prevention of overdose instances.
  - ∉ Develop a Medicaid/KASPER interface
- ü KASPER program requests increase to 122,469.

2003
- ü Development of enhanced KASPER begins after $1.4M funding initiative from legislature.
- ü KASPER program requests increase to 109,442.
- ü Legislative Prescription Drug Abuse Task Force produced a report leading to SB14 making modifications to KRS 218A.202.

2002
KASPER program requests increase to 95,032.

2001
KASPER program requests increase to 71,381.

2000
KASPER program requests increase to 36,172.

1999
KASPER program begins in July with 3,105 requests processed in the first six months.

1998
Legislature passes KASPER legislation and Governor signs into law.

1997
Attorney General's Task Force recommends KASPER program.

STATE STATUTE

KRS 218A.202

Electronic system for monitoring controlled substances - Penalty for illegal use of system - Pilot project - Continuing education programs

218A.202 Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.

(1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy.

(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.

(6) The Cabinet for Health Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;

(f) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or

(g) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.

(7) The Department for Medicaid Services may use any data or reports from the system for the purpose of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician.

(8) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction, except that:

(a) A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section, or with a law enforcement officer designated in paragraph (b) of subsection (6) of this section; and

(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

(9) The Cabinet for Health Services, all peace officers specified in subsection (6)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(10) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

(11) Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.

(12) Knowing disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.

(13) The Governor's Office for Technology, in consultation with the Cabinet for Health Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:

(a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and

(b) Study the use of an interactive system that includes a relational data base with query capability.

(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.

(15) The Cabinet for Health Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

(16) (a) The Cabinet for Health Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.

(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

(c) The cabinet shall work with the Justice Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.

Effective: July 13, 2004

History: Amended 2004 Ky. Acts ch. 68, sec. 1, effective July 13, 2004; and ch. 107, sec. 1, effective July 13, 2004. -- Amended 2002 Ky. Acts ch. 295, sec. 1, effective April 9, 2002. -- Created 1998 Ky. Acts ch. 301, sec. 13, effective July 15, 1998.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts. chs. 68 and 107. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts. ch. 107, which was last enacted by the General Assembly, prevails under KRS 446.250.

STATE REGULATION

902 KAR 55:110
Monitoring system for prescription controlled substances

902 KAR 55:110. Monitoring system for prescription controlled substances.

RELATES TO: KRS 218A.202

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.202, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202 directs the Cabinet for Health Services to establish an electronic system for monitoring Schedule II, III, IV, and V controlled substances that are dispensed in the Commonwealth or dispensed to an address within the Commonwealth. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. Also the system will enable regulatory or law enforcement agencies to address violations of KRS Chapter 218A. The purpose of this administrative regulation is to establish the criteria for reporting prescription data, for providing reports to authorized persons, and for a waiver for a dispenser who does not have an automated recordkeeping system.

Section 1. Definitions. (1) "Patient identifier" means a patient's:

(a) Full name;

(b) Address, including zip code;

(c) Date of birth; and

(d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.

(2) "Pharmacy Universal Claim Form" means a form that:

(a) Is in the format of the "Pharmacy Universal Claim Form" incorporated by reference in Section 6 of this administrative regulation; and

(b) Contains the information specified by Section 2(2) of this administrative regulation.

(3) "Report" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance.

Section 2. Data Reporting. (1) A dispenser shall report all controlled substances dispensed after December 31, 1998.

(2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:

(a) Patient identifier;

(b) National drug code of the drug dispensed;

(c) Metric quantity of drug dispensed;

(d) Date of dispensing;

(e) Estimated days supply dispensed;

(f) Drug Enforcement Administration registration number of the prescriber;

(g) Serial number assigned by the dispenser; and

(h) The Drug Enforcement Administration registration number of the dispenser.

(3)(a) The data shall be transmitted within sixteen (16) days of the date of dispensing unless the cabinet grants an extension.

(b) An extension may be granted if a dispenser suffers a mechanical or electronic failure, or cannot meet the deadline established by paragraph (a) of this subsection for other reasons beyond his control. A dispenser shall apply in writing for an extension. An application for an extension shall state the reason why an extension is required, and the period of time for which the extension is required.

(c) An extension shall be granted to all dispensers if the cabinet or its agent is unable to receive electronic reports.

(4) Except as provided in subsection (7) of this section, the data shall be transmitted by:

(a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;

(b) Double sided, high density micro floppy disk; or

(c) One-half (1/2) inch nine (9) track 1600 or 6250 BPI magnetic tape.

(5) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances".

(6) The cabinet shall provide a toll-free telephone number for transmitting electronic reports by modem.

(7)(a) A dispenser, who does not have an automated recordkeeping system capable of producing an electronic report in the format established by "ASAP Telecommunications Format for Controlled Substances", may request a waiver from electronic reporting. The request shall be made to the cabinet in writing.

(b) A dispenser shall be granted a waiver, if he agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form".

Section 3. Compliance. (1) A dispenser shall be deemed to be the person who is registered with the U.S. Drug Enforcement Administration.

(2) A dispenser may presume that the patient identification information provided by the patient or the patient's agent is correct.

Section 4. Request for Report. (1) A written request shall be filed with the cabinet prior to the release of a report.

(2) A request for a report shall be made on Request for KASPER Report, Form DCB-15 except for a subpoena issued by a grand jury.

Section 5. Alternative Patient Identification Number. (1) If a patient does not have a Social Security number, or refuses to provide a Social Security number, the patient's driver's license number shall be used.

(2) If a patient does not have a Social Security number or a driver's license number, the number 000-00-0000 shall be used.

(3) The number "999-99-9999" shall be used if a patient or a patient's agent refuses to provide a Social Security number or driver's license number.

(4) If a patient is a child who does not have a Social Security number, the Social Security number, driver's license number, or the number "000-00-0000", as applicable, of the parent or guardian shall be used.

(5) If a patient is an animal, the owner's Social Security number, or driver's license number, or the number "000-00-0000", as applicable shall be used.

(6) If a patient's Social Security number is not available, the Social Security number, or driver's license number, or the number "000-00-0000", as applicable, of the person obtaining the controlled substance on behalf of the patient shall be used.

(6) If the patient or the patient's agent refuses to provide a Social Security number or driver's license, the number 999-99-9999 shall be used.

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "ASAP Telecommunications Format for Controlled Substances", American Society for Automation in Pharmacy, May, 1995;

(b) "Pharmacy Universal Claim Form"; and

(c) "Request for KASPER Report, DCB-15, 9-98".

(2) This material may be inspected, copied, or obtained at the Department for Public Health, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (25 Ky.R. 966; Am. 1367; eff. 12-16-98.)

DRUG ENFORCEMENT/ KASPER FAQs

KASPER FAQs

1. What is KASPER?
   - ∉ "Kentucky All Schedule Prescription Electronic Reporting" ~ A database of all of the controlled substance prescriptions filled in Kentucky.

2. Why would controlled substance prescriptions I write for an individual not appear on the KASPER report?
   - ∉ The three most common reasons are (1) the patient cannot be identified because of erroneous information given to the dispenser; (2) the dispenser is not reporting to the KASPER system; or (3) the patient is going across state lines to fill the prescriptions.

3. I faxed a request for a KASPER report into the KASPER office two hours ago and I have not received a response.
   - ∉ Under the original system (prior to eKASPER), it would sometimes take incoming faxes over an hour to come into the KASPER office because of the high volume of requests. The request was logged, the report run and faxed back. The fax systems in the KASPER office would often have over 100 pages queued up - taking between one and two hours to clear. The total time involved would easily be four or more hours; KASPER staff often receives more than 600 requests per day. Under the enhanced system, the web-based system will allow a requestor to avoid these delays and the report should turn around in very short order.

4. Who may request a KASPER report?
   - ∉ A physician for the medical treatment of an existing or prospective patient, a pharmacist for pharmaceutical treatment, a law enforcement officer with an active investigation, a licensure board for a licensee, Medicaid for a Medicaid recipient, a grand jury by subpoena, and a court order by a judge of competent jurisdiction.

5. What is on a KASPER report?
   - ∉ A KASPER report will show all the scheduled prescriptions a patient has had for the specified time period, as well as the doctor who prescribed them and dispenser who dispensed them.

6. Will out of state prescriptions show up on a KASPER report?
   - ∉ Pharmacies licensed by the Kentucky Board of Pharmacy are required to report any controlled substance prescriptions dispensed to the KASPER program. The Kentucky Board of Pharmacy licenses mail order pharmacies, so their data should be available.

7. What can I do with the report?
   - ∉ A physician may discuss the information contained in the report with the patient for whom the report was run, with another physician treating the patient, the pharmacy responsible for dispensing the medication or with law enforcement if there is cause. However, a physician or any other authorized user may not send or share the report with anyone unless specifically allowed in KRS 218A.202.

8. I have a patient that had a prescription last week, why is that not on there?
   - ∉ It takes 30 to 45 days for information to appear in KASPER. A dispenser has 16 days from the filling date to report the information to our contractor. The contractor has two weeks to send the information to the KASPER staff. Anticipated regulatory changes will cut the data delay in half.

9. Who benefits the most from the enhancements that have been made to the system?
   - ∉ Ultimately, the citizens of the Commonwealth will benefit the most. Physicians and pharmacists can make better treatment decisions with this information while the patients and customers are on the premises. Investigations by law enforcement personnel will proceed much faster, safeguarding our health care dollars and making the Commonwealth a safer place to live.

10. How is this information safeguarded so that only physicians, pharmacist and law enforcement have access?
    - ∉ The enhanced system requires an extensive registration process and the data provided by the enrolling entity is verified by independent source systems.

HIPAA FAQs

HHS Office for Civil Rights Answers To Frequently Asked Questions

(Posted on OCR Website at www.os.dhhs.gov/ocr/hipaa/)

Question

Will this HIPAA Privacy Rule make it easier for police and law enforcement agencies to get my medical information?

Answer (Posted 3-3-03)

No. The Rule does not expand current law enforcement access to individually identifiable health information. In fact, it limits access to a greater degree than currently exists, since the Rule establishes new procedures and safeguards that restrict the circumstances under which a covered entity may give such information to law enforcement officers.

For example, the Rule limits the type of information that covered entities may disclose to law enforcement, absent a warrant or other prior process, when law enforcement is seeking to identify or locate a suspect. It specifically prohibits disclosure of DNA information for this purpose, absent some other legal requirements such as a warrant. Similarly, under most circumstances, the Privacy Rule requires covered entities to obtain permission from persons who have been the victim of domestic violence or abuse before disclosing information about them to law enforcement. In most States, such permission is not required today.

Where State law imposes additional restrictions on disclosure of health information to law enforcement, those State laws continue to apply. This Rule sets a national floor of legal protections; it is not a set of "best practices."

Even in those circumstances when disclosure to law enforcement is permitted by the Rule, the Privacy Rule does not require covered entities to disclose any information. Some other Federal or State law may require a disclosure, and the Privacy Rule does not interfere with the operation of these other laws. However, unless the disclosure is required by some other law, covered entities should use their professional judgment to decide whether to disclose information, reflecting their own policies and ethical principles. In other words, doctors, hospitals, and health plans could continue to follow their own policies to protect privacy in such instances.

Question

When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?

Answer (Posted 7-26-04)

The Privacy Rule is balanced to protect an individual's privacy while allowing important law enforcement functions to continue. The Rule permits covered entities to disclose protected health information (PHI) to law enforcement officials, without the individual's written authorization, under specific circumstances summarized below. For a complete understanding of the conditions and requirements for these disclosures, please review the exact regulatory text at the citations provided. Disclosures for law enforcement purposes are permitted as follows:

- *To comply with a court order or court-ordered warrant, a subpoena or summons issued by a judicial officer, or a grand jury subpoena.* The Rule recognizes that the legal process in obtaining a court order and the secrecy of the grand jury process provides protections for the individual's private information (45 CFR 164.512(f)(1)(ii)(A)-(B)).

- *To respond to an administrative request*, such as an administrative subpoena or investigative demand or other written request from a law enforcement official. Because an administrative request may be made without judicial involvement, the Rule requires all administrative requests to include or

be *accompanied by a written statement that the information requested is relevant and material, specific and limited in scope, and de-identified information cannot be used* (45 CFR 164.512(f)(1)(ii)(C)).

- *To respond to a request for PHI for purposes of identifying or locating a suspect, fugitive, material witness or missing person; but the covered entity must limit disclosures* of PHI to name and address, date and place of birth, social security number, ABO blood type and rh factor, type of injury, date and time of treatment, date and time of death, and a description of distinguishing physical characteristics. Other information related to the individual's DNA, dental records, body fluid or tissue typing, samples, or analysis cannot be disclosed under this provision, but may be disclosed in response to a court order, warrant, or written administrative request (45 CFR 164.512(f)(2)).

This same limited information may be reported to law enforcement:

  - *About a suspected perpetrator of a crime when the report is made by the victim who is a member of the covered entity's workforce* (45 CFR 164.502(j)(2));
  - *To identify or apprehend an individual who has admitted participation in a violent crime* that the covered entity reasonably believes may have caused serious physical harm to a victim, provided that the admission was not made in the course of or based on the individual's request for therapy, counseling, or treatment related to the propensity to commit this type of violent act (45 CFR 164.512(j)(1)(ii)(A), (j)(2)-(3)).

- *To respond to a request for PHI about a victim of a crime, and the victim agrees.* If, because of an emergency or the person's incapacity, the individual cannot agree, the covered entity may disclose the PHI if law enforcement officials represent that the PHI is not intended to be used against the victim, is needed to determine whether another person broke the law, the investigation would be materially and adversely affected by waiting until the victim could agree, and the covered entity believes in its professional judgment that doing so is in the best interests of the individual whose information is requested (45 CFR 164.512(f)(3)).

Where child abuse victims or adult victims of abuse, neglect or domestic violence are concerned, other provisions of the Rule apply:

  - *Child abuse or neglect may be reported* to any law enforcement official authorized by law to receive such reports and the agreement of the individual is not required (45 CFR 164.512(b)(1)(ii)).
  - *Adult abuse, neglect, or domestic violence may be reported* to a law enforcement official authorized by law to receive such reports (45 CFR 164.512(c)):
    - If the individual agrees;
    - If the report is required by law; or
    - If expressly authorized by law, and based on the exercise of professional judgment, the report is necessary to prevent serious harm to the individual or others, or in certain other emergency situations (see 45 CFR 164.512(c)(1)(iii)(B)).
    - Notice to the individual of the report may be required (see 45 CFR 164.512(c)(2)).

- *To report PHI to law enforcement when required by law* to do so (45 CFR 164.512(f)(1)(i)). For example, state laws commonly require health care providers to report incidents of gunshot or stab wounds, or other violent injuries; and the Rule permits disclosures of PHI as necessary to comply with these laws.

- *To alert law enforcement to the death of the individual*, when there is a suspicion that death resulted from criminal conduct (45 CFR 164.512(f)(4)).
  - Information about a decedent may also be shared with *medical examiners or coroners to assist them in identifying the decedent, determining the cause of death, or to carry out their other authorized duties* (45 CFR 164.512(g)(1)).

- *To report PHI that the covered entity in good faith believes to be evidence of a crime that occurred on the covered entity's premises* (45 CFR 164.512(f)(5)).

- *When responding to an off-site medical emergency, as necessary to alert law enforcement about criminal activity*, specifically, the commission and nature of the crime, the location of the crime or any victims, and the identity, description, and location of the perpetrator of the crime (45 CFR 164.512(f)(6)). This provision does not apply if the covered health care provider believes that the individual in need of the emergency medical care is the victim of abuse, neglect or domestic violence; see above *Adult abuse, neglect, or domestic violence* for when reports to law enforcement are allowed under 45 CFR 164.512(c).

- When consistent with applicable law and ethical standards:
  - To a law enforcement officially reasonably able *to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public* (45 CFR 164.512(j)(1)(i)); or
  - *To identify or apprehend an individual who appears to have escaped from lawful custody* (45 CFR 164.512(j)(1)(ii)(B)).

- *For certain other specialized governmental law enforcement purposes*, such as:
  - *To federal officials authorized to conduct* intelligence, counter-intelligence, and other *national security activities* under the National Security Act (45 CFR 164.512(k)(2)) or *to provide protective services* to the President and others and conduct related investigations (45 CFR 164.512(k)(3));
  - *To respond to a request for PHI by a correctional institution or a law enforcement official having lawful custody* of an inmate or others if they represent such PHI is needed to provide health care to the individual; for the health and safety of the individual, other inmates, officers or employees of or others at a correctional institution or responsible for the transporting or transferring inmates; or for the administration and maintenance of the safety, security, and good order of the correctional facility, including law enforcement on the premises of the facility (45 CFR 164.512(k)(5)).

Except when required by law, the disclosures to law enforcement summarized above are subject to a minimum necessary determination by the covered entity (45 CFR 164.502(b), 164.514(d)). When reasonable to do so, the covered entity may rely upon the representations of the law enforcement official (as a public officer) as to what information is the minimum necessary for their lawful purpose (45 CFR 164.514(d)(3)(iii)(A)). Moreover, if the law enforcement official making the request for information is not known to the covered entity, the covered entity must verify the identity and authority of such person prior to disclosing the information (45 CFR 164.514(h)).

Question

Does the HIPAA Privacy Rule permit covered entities to disclose protected health information, without individuals' authorization, to public officials responding to a bioterrorism threat or other public health emergency?

Answer (Posted 3-11-03)

Yes. The Rule recognizes that various agencies and public officials will need protected health information to deal effectively with a bioterrorism threat or emergency. To facilitate the communications that are essential to a quick and effective response to such events, the Privacy Rule permits covered entities to disclose needed information to public officials in a variety of ways. Covered entities may disclose protected health information, without the individual's authorization, to a public health authority acting as authorized by law in response to a bioterrorism threat or public health emergency (see 45 CFR 164.512(b), public health activities). The Privacy Rule also permits a covered entity to disclose protected health information to public officials who are reasonably able to prevent or lessen a serious and imminent threat to public health or safety related to bioterrorism (see 45 CFR 164.512(j), to avert a serious threat to health or safety). In addition, disclosure of protected health information, without the individual's authorization, is permitted where the circumstances of the emergency implicates law enforcement activities (see 45 CFR 164.512(f)); national security and intelligence activities (see 45 CFR 164.512(k)(2)); or judicial and administrative proceedings (see 45 CFR 164.512(e)).

POWERPOINT PRESENTATIONS

KASPER to eKASPER

Taking The Premier Prescription Monitoring Program To Even Greater Heights

Kentucky
UNBRIDLED SPIRIT

KENTUCKY

ALL

SCHEDULE

PRESCRIPTION

ELECTRONIC

REPORTING

Kentucky
UNBRIDLED SPIRIT

Kentucky All Schedule Prescription Electronic Reporting

1997
Attorney General's Task Force recommends KASPER program.

1998
Legislature passes KASPER legislation and Governor signs into law.

1999
KASPER program begins in July with 3,105 requests processed in the first six months.

Kentucky All Schedule Prescription Electronic Reporting

2000
KASPER program requests increase to 36,172

2001
KASPER program requests increase to 71,381

2002
KASPER program requests increase to 95,032

Cabinet for Health and Family Services

Kentucky All Schedule Prescription Electronic Reporting

2003

Development of enhanced KASPER begins after $1.4M funding initiative from legislature.

KASPER program requests increase to 109,442

Legislative Prescription Drug Abuse Task Force produced a report leading to SB14 making modifications to KRS 218A.202

Kentucky All Schedule Prescription Electronic Reporting

2004

•Governor Fletcher signs SB14 into law
•Drug Enforcement and Professional Practices Branch moved from the Department for Public Health to The Office of the Inspector General, Division of Fraud, Waste and Abuse/Identification and Prevention
•OIG assumes responsibility for the continued development of eKASPER and administration of the 2004 Hal Rogers Grant

Cabinet for Health and Family Services

Kentucky All Schedule Prescription Electronic Reporting

2004 Continued

- 2004 Hal Rogers Grant
  - Survey KASPER system users
  - Form focus/work groups to study KASPER
  - Contract with Kentucky Injury Prevention and Research Center to determine effectiveness of KASPER in prevention of overdose instances.
  - Develop a Medicaid/KASPER interface
- KASPER program requests increase to 122,469

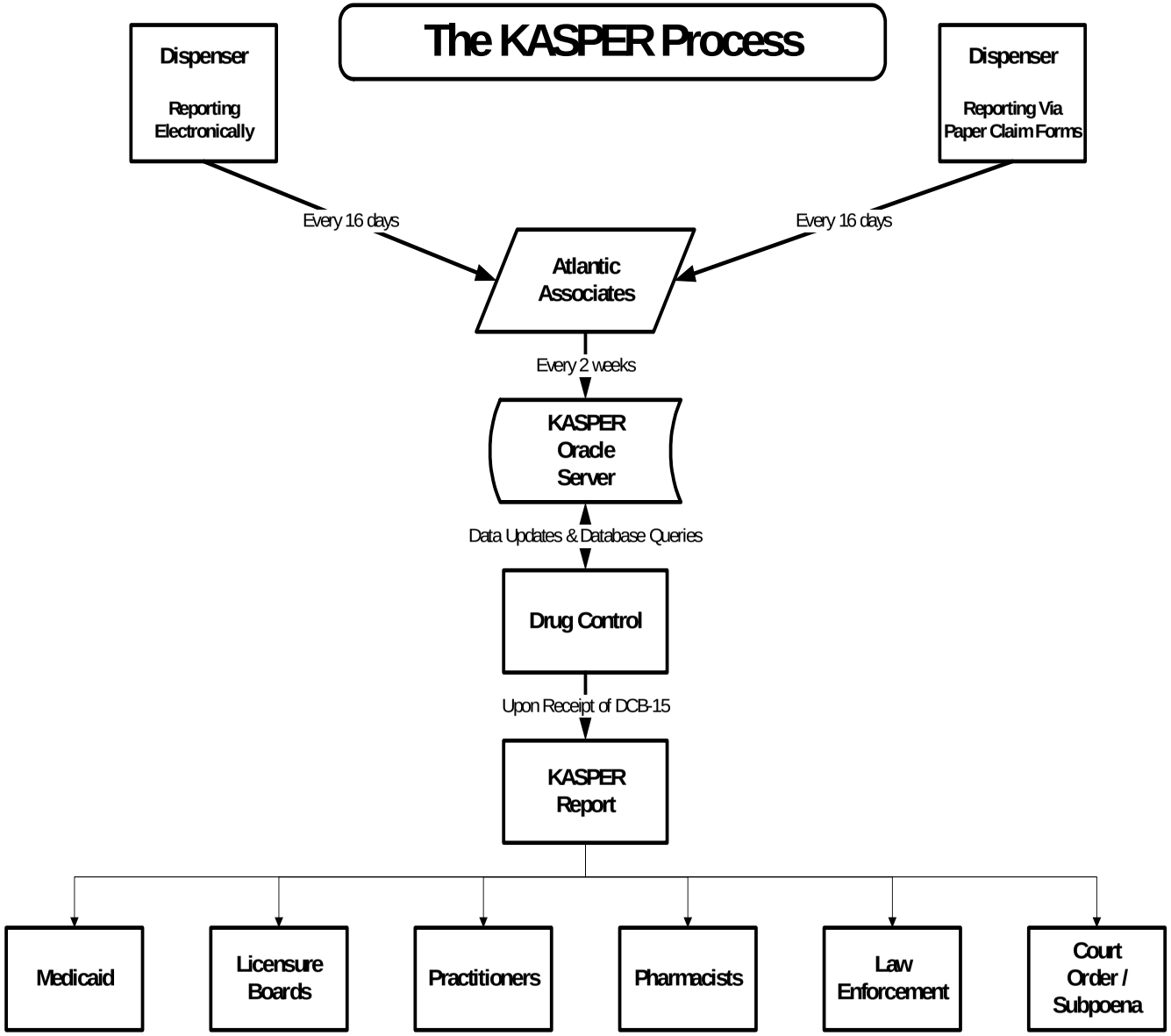
Kentucky All Schedule Prescription Electronic Reporting

2005

- eKASPER implementation
- 2004 Hal Rogers Grant will be completed June 30, 2005 and report submitted to DOJ
- 2005 Hal Rogers Grant application submitted
  - Isolate KASPER technical issues
  - Develop a means to monitor KASPER system access by authenticating user IDs
  - Develop trend reports from KASPER data
  - Streamline KASPER staff business processes to maximize effectiveness.

Cabinet for Health and Family Services

Flow Chart For The Original KASPER System



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The Economics of Drug Diversion

"Legal" Drugs Have Street Values

Generic Name	Brand Name	Brand Cost/ 100	Street Value Per 100
Acetaminophen w Codeine 30mg	Tylenol #3	$56.49	$800.00
Diazepam 10 mg	Valium 10 mg	$298.04	$1,000.00
Fentanyl Patch/5	Duragesic Patches	$243.59	$400.00
Hydromorphone	Dilaudid 4 mg	$88.94	$10,000.00
Methylphenidate	Ritalin	$88.24	$1,500.00
Oxycodone	Oxycontin 80 mg	$1,081.36	$8,000.00

Goldman, MD, Brian, "Unmasking the Illicit Drug Seeker"

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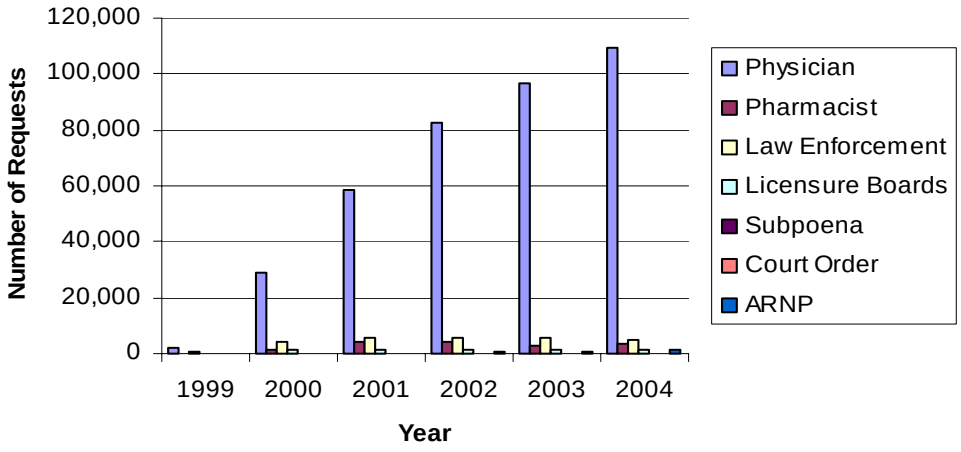
By Logging The Requestor Information For Each Report Request

KASPER Requests Per Year By Type of Requestor



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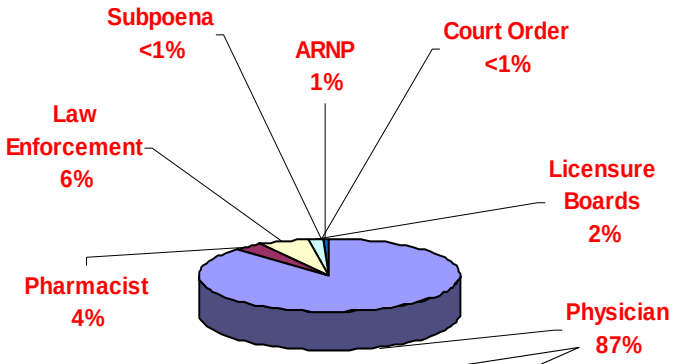
By Logging The Requestor Information For Each Report Request

Percentage of Requests By Type Between 1/1/1999 and 12/31/2004



Even with 87% of the total KASPER reports being run by physicians, we estimate less than 50% of the physicians prescribing controlled substances are using the system

KASPER Then And Now

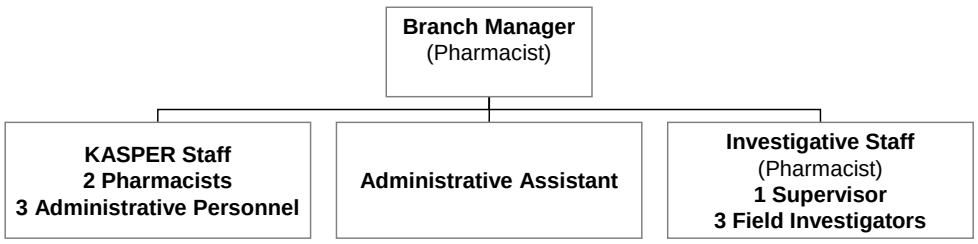
The System was designed to produce 2,000 reports per year

Currently producing in excess of 2,500 reports per week

With Almost 450,000 KASPER Report Requests Processed In Five Years The Usefulness of The Program Has Been Validated

When KASPER Began In 1999 It Was Anticipated One Staff Person Would Be Required To Administer The Program

Today The Drug Enforcement And Professional Practices Branch Has Five Full Time Personnel Dedicated To KASPER Report Processing



With The Original KASPER System

- **The high volume of report requests processed caused delays**
- **It routinely took over four hours to receive a KASPER report**
- **It has sometimes taken weeks to receive a KASPER report**

Thus the need for enhancement

Enhanced KASPER
eKASPER

Web Access to KASPER Reports

Presented by: Christopher J. Miller, MA

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Goals of Enhancements

Automate

Automate

Automate

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Goals of Enhancements

- WEB self service.
- Automate the report creation process. Goal 80%
- Real-time access to data.
- Automate distribution.
- Reduce number of faxes.
- Reduce paper created by 90%.
- Decrease lag time for obtaining new data.

Challenges

- No WEB model for PMP.
- Credentialing WEB users:
  - Doctors
  - Pharmacists
  - Law Enforcement
- Compliance with HIPAA & state law
  KRS218A.202

Challenges, continued

- Secure delivery of reports:
  - Fax (HIPAA Compliant)
  - eMail (determined not secure for our purposes)
  - WEB Interface (secure logon)
- Data …. accuracy, quality, integrity.
- Faxing is a time-consuming, costly process even if automated.
- Must manage user acceptance.

Results of Enhancements

- 90% of paperwork reduced.
- More than half of the work cut out.
- Initial results show that approximately 80% of all reports are ready within 15 minutes. Many in less than a minute.

Quality Safeguards

Reports forced to review are prepared by KASPER staff pharmacists.

Reports are forced to review, if:

- More than six pages
- Multiple dates of birth
- More than one last name

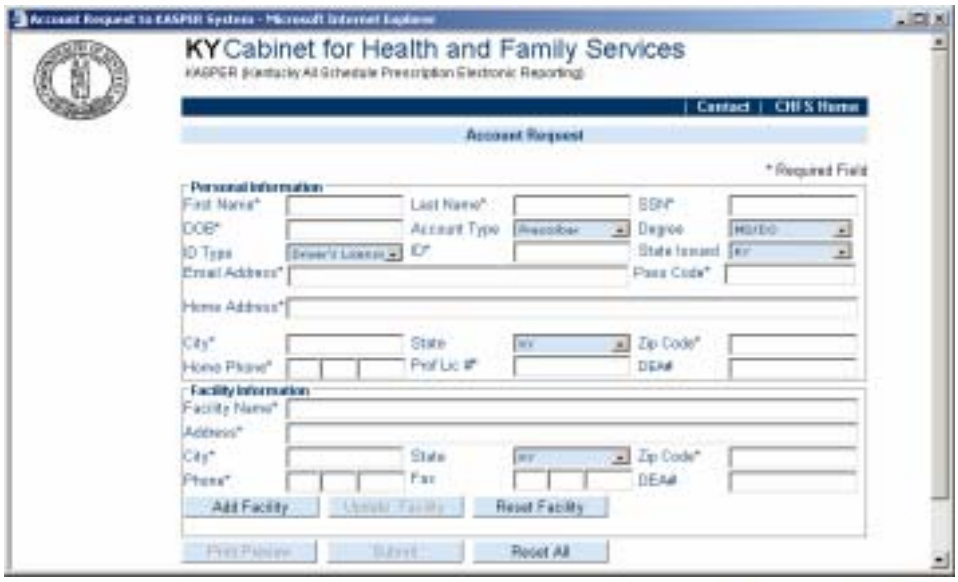
Account Request

- To request an account, use the URL below:

  https://ekasper.chfs.ky.gov/accessrequest

- Safe and secure for both the user and the Commonwealth.

Account Request Page



Report Request

- Via secure WEB application.
- Application accessible from any PC with WEB access.
- Doctors and Pharmacists can receive a report within 15 minutes.
- Available 24 / 7 .
- URL: https://ekasper.chfs.ky.gov

Scenario One

- It is 2:00 a.m. in the county hospital ER.
- A patient has presented with symptoms of a kidney stone. The patient informs the physician he is allergic to anti-inflammatory drugs, but that he always responds well to Tylox, a powerful narcotic.

Before eKASPER

- A KASPER report may have been requested by fax.
- The report would have been returned the next business day.

After eKASPER

- The ER physician requests a KASPER report on the patient.
- Within 15 minutes, the physician confirms that the patient is receiving similar drugs from multiple physicians.

Scenario Two

- A patient presents a controlled substance prescription to a neighborhood pharmacy at 7:30 pm.
- The pharmacy staff gets the patient's address, social security number and date of birth, then proceeds to fill the prescription.
- When the prescription is filled and sent to the insurance company for adjudication, the pharmacy receives a message saying the prescription is being filled too soon and it was filled at another pharmacy.

Red Flag

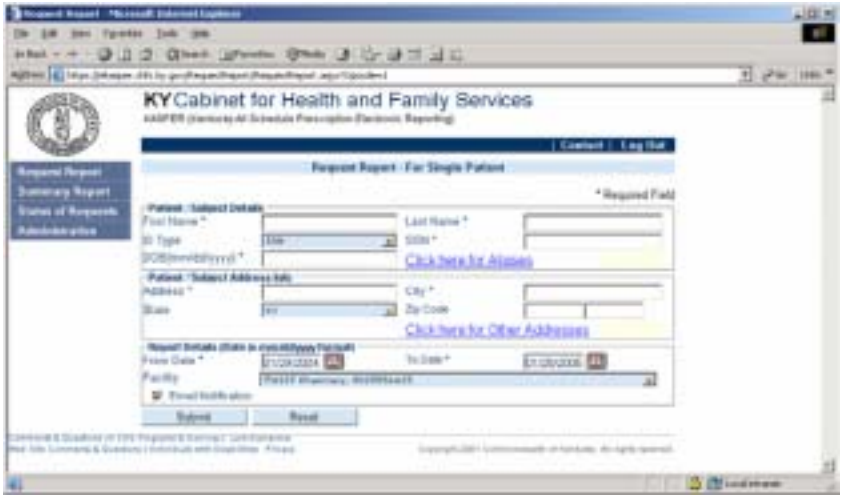
Before eKASPER

- A KASPER report may have been requested by fax.
- The report would have been returned the next business day.
- By the time the pharmacist received the report, the only option would have been to notify the prescribing physician and suggest they obtain a KASPER report on the patient.

After eKASPER

- KASPER report requested online while patient is still in the pharmacy.
- KASPER report delivered within 15 minutes.
  - 80 % of the time.
  - Many reports are returned in a minute or less.
- The KASPER reports shows that the patient is receiving the same drug from multiple doctors and at multiple pharmacies.
- The pharmacist refuses to fill the prescription.
- The pharmacist would then contact the prescribing physician and law enforcement regarding the patient.

eKASPER Report Request



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RESOURCE LIST

Resource List

1To request an eKASPER web account log onto:

https://ekasper.chfs.ky.gov/accessrequest

1For questions and help using our website:

Email us at: ekasperhelp@ky.gov

Help Desk: (502) 573-0361

1For KASPER program questions and help:

Drug Enforcement & Professional Practices Branch

(502) 564-7985

Or visit our web site:

http://chfs.ky.gov/oig/dfwaip.htm